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### **CERTIFICATE OF FIRST-CLASS MAILING**

Attorney Docket No. : 202.2D2

Applicant(s) : Clarence N. Ahlem, et al

For : Pharmaceutical Compositions and Treatment

Methods

Application serial No.: 10/602,330

Attorney : Daryl D. Muenchau, Registration No. 36,616

Date of Deposit : May 24, 2005

I hereby certify that the accompanying Transmittal, Information Disclosure Statement, 28 references, and return postage prepaid postcard are being deposited with the United States Postal Service First-Class Mail Post Office to Addressee service, pursuant to 37 CFR § 1.8, on the date indicated above and are addressed to the U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450, Mail Stop Amendment.

Brenda Mannon-Freeman



## PATENT Docket No. 202.2D2

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**Applicant** 

: Clarence N. Ahlem, et al.

Application No.

: 10/602,330

Filed

: June 23, 2003

Title

: Pharmaceutical Compositions and Treatment Methods

Examiner

: Barbara P. Badio

Group Art Unit

: 1617

Customer No. Confirmation No.

: 26551: 9052

# INFORMATION DISCLOSURE STATEMENT TRANSMITTAL

Mail Stop: Amendment Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

#### Dear Sir:

Enclosed is form PTO-1449 listing 28 references that are also enclosed. No fee is required in accordance with 37 C.F.R. § 1.97(b).

Respectfully submitted,

HOLLIS-EDEN PHARMACEUTICALS, INC.

Dated: May 24, 2005

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Customer No. 26,551

FORM PTO-1449			
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INFORMATION			
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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO. APPLICATION NO. 202.2D2 10/602,330

DISCLOSURE STATEMENT Y APPLICANT

APPLICANT

MAY 2 7 2005 L. (USE SEVERAL SHEETS IF NECESSARY)

Clarence N. Ahlem, et al

FILING DATE June 23, 2003 GROUP 1617

U.S. PATENT DOCUMENTS							
EXAMINER Approval Date		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)
		U.	S. PATENT APPL	ICATION PUBLICATION DO	DCUMENTS		
EXAMINER INITIAL	.	DOCUMENT SERIAL NUMBER	NAME		CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)

			FOREIGN PATENT DOCUMENTS		,		
EXAMINER Approval Date	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSL	-ATION
						YES	NO
					<u>l</u>		

EXAMINER Approval Date	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
	Araghi-Niknam et al., Modulation of immune dysfunction during murine leukaemia retrovirus infection of old mice by dehyroepiandrosterone sulphate (DHEAS), <i>Immunology</i> 90:344-349 (1997)
	Byron J, Nature of the erythropoietin-independent response of CFU-S to steroids, Exp. Hematol. 8:160-167 (1980)
	Byron J, Manipulation of the cell cycle of the hemopoietic stem cell, Exp. Hemat. 3:44-53 (1975)
	Crandall et al., Estrogens and hematopoiesis: characterization and studies on the mechanism of neutropenia, <i>J. Lab. Clin. Med.</i> 95(6):857-867 (1980)
	Evens et al., Androgens and erythropoieseis, <i>The J. of Clin. Pharmacology</i> pps. 94-101 (1974)
	Gianotti et al., Steroid therapy can modulate gut barrier function, host defense and survival in thermally injured mice, <i>J Surg Research</i> 62:53-58 (1996)
	Horn, Y., The effect of androgenic hormones on bone marrow of rats receiving chemotherapy, Oncology 25:512-519 (1971)
	Kang et al., Dehydroepiandrosterone and β-endorphin enhance IL-12 gene expression, <i>Taehan Misaengmulhak Hoechi (J. Korean Soc. Microbiology)</i> 31(4):399-404 (1996) (translation from Korean)
	Lardy et al., Ergosteroids II: Biologically active metabolites and synthetic derivatives of dehydroepiandrosterone, <i>Steroids</i> 63:158-165 (1998)

EXAMINER	DATE CONSIDERED

\*EXAMINER: INITIAL IF CITATION CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED, INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.

FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO. 202.2D2

APPLICATION NO. 10/602,330

### INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(USE SEVERAL SHEETS IF NECESSARY)

APPLICANT
Clarence N. Ahlem, et al

FILING DATE
June 23, 2003

GROUP 1617

EXAMINER Approval Date	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)					
	Leroy et al., Estrogen-like effect of 5-androstene-3ß, 17ß-diol on the induction of fetal thymidine kinase in the rat uterus, <i>J. Steroid Biochem</i> 31(4):453-458 (1988)					
	Loria et al., Mobilization of cutaneous immunity for systemic protection against infections, Ann NY Acad Sci 650:636-666 (1992)					
	Loria et al., Regulation of the immune response by dehydroepiandrosterone and its metabolites, <i>J. Endocrinology</i> , 150:S209-S220 (1996)					
	Manz et al., Methyl 17ß-Carboxyester Derivatives of Natural and Synthetic Glucocorticoids: Correlation Between Receptor Binding and Inhibition of in vitro Phytohaemagglutinin-Induced Lymphocyte Blastogenesis, J. Clin. Chem. Clin. Biochem. 21(2):69-75 (1983)					
	Navarro et al., Androgen therapy for anemia in elderly uremic patients, Int'l Urology and Nephrology 32:549-557 (2001)					
	Padgett et al., Endocrine regulation of murine macrophage function: effects of dehydroepiandrosterone, androstenediol, and androstenetriol, <i>J of Immunology</i> 84:61-68 (1998)					
	Padgett et al., Endocrine regulation of the immune response to influenza virus infection with a metabolite of DHEA-androstenediol, <i>J. of Neuroimmunology</i> 78:203-211 (1997)					
	Padgett et al., In vitro potentiation of lymphocyte activation by dehydroepiandrosterone, androstenediol and androstenetriol, <i>J. Immuno</i> l 153(4):1544-1552 (1994)					
	Padgett et al., Steroid hormone regulation of a polyclonal T <sub>H</sub> 2 immune response, Ann NY Acad Sci 774:323-325 (1995)					
	Pashko, L. et al., "Inhibition of DNA synthesis in mouse epidermis and breast epithelium by dehydroepiandrosterone and related steroids", Carcinogenesis, Vol. 2, No. 8, p. 717-721 (1981)					
	Rosenblum et al., Androgenic hormones and human granulopoiesis in vitro, Blood 43:351-356 (1974)					
	Sanchez-Medal, L., The hemopoietic action of androstanes, <i>Progress in Hematology</i> , pps. 111-136					
	Sigg et al., 3α-Acetoxyätien-(8:9 oder 8:14)-säure-methylester, Helvetica Chimica Acta, 39(6):1507-1525 (1956) (translation from German)					
	Steinzherz et al., Effect of lithium carbonate plus oxymetholone vs. lithium alone on chemotherapy-induced myelosuppression, <i>The American J of Pediatric Hematology/Oncology</i> 5(1):39-44 (1983)					
	Weisz et al., Selective reactions of some steroids with diethyl dicarbonate, Archiv der Pharmazie 319:952-953 (1986)					
	Whitnall et al., Androstenediol stimulates myelopoiesis but not lymphopoiesis in irradiated mice, Blood 90(10)(1), 175a (1997)					
	Whitnall et al., Androstenediol stimulates myelopoiesis and enhances resistance to infection in gamma-irradiated mice, Int'l J of Immunopharmacology 22:1-14 (2000)					
	Whitnall et al., In Vivo radioprotection by 5-androstenediol: Stimulation of the immune system, Radiation Research 156:283-293 (2001)					
	Yang et al., Inhibition of HIV-1 Latency Reactivation by Dehydroepiandrosterone (DHEA) and an Analog of DHEA, Aids Research and Human Retroviruses 9(8):747-754 (1993)					

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